

REMARKS

I. Status of the Claims

Claims 1, 3 – 15 and 17 – 33 are pending in application. Claims 7, 11 – 13, 31 and 32 are withdrawn from consideration. Claims 1, 3 – 6, 8 – 10, 14, 15, 17 – 30 and 33 are rejected. Claims 2 and 16 are canceled; however, claim 2 is re-presented above in amended form as new claim 34. Applicants request reconsideration of the application, including new claim 34 which re-presents original claim 2 in amended form, in view of the amendments presented above and the remarks presented below.

II. Amendment to the Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. The objection is respectfully traversed in view of the foregoing amendments whereby Applicants have deleted the embedded hyperlinks and/or other form of browser-executable code. Accordingly, the objection is deemed to be overcome.

III. New Drawings Are Submitted Herewith

The examiner requires new corrected drawings in compliance with 37 CFR 1.121(d). New drawings are submitted herewith.

IV. Claims 1, 3 – 6, 17–19 and 33 are Patentable Under 35 U.S.C. § 101

Claims 1, 3-6, 17-19 and 33 are rejected under 35 U.S.C. § 101. The Examiner contends that the claimed invention of the subject claims is directed to non-statutory subject matter. Claims 17 and 18 have been canceled. The rejection of claims 1, 3-6, 19, and 33 is respectfully

traversed.

Applicants appreciate the Examiner's suggestion that the claims be amended to read "isolated nucleic acid" to overcome the rejection. The subject claims have been amended in accordance with the Examiner's suggestion. Accordingly, the rejection is deemed to be overcome.

IV. The Rejection of Claim 30 Under 35 U.S.C. § 112, Second Paragraph

Claim 30 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 30 has been canceled, which moots the rejection.

V. The Rejection of Claims 1, 3, 4, 6, 8-10, 14, 15, 17-30 and 33 Under 35 U.S. C. § 112 -
Written Description

Claims 1, 3, 4, 6, 8-10, 14, 15, 17-30 and 33 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 17, 18, and 30 have been canceled. The rejection of claims 1, 3, 4, 6, 8-10, 15, 19-29, and 33 is respectfully traversed.

To advance prosecution, claim 1 is amended to recite an isolated nucleic acid "encoding *Tetrahymena* delta-6-desaturase as shown in SEQ ID NO:2." The specification discloses the *Tetrahymena* delta-6-desaturase as shown in SEQ ID NO:2. Those skilled in the art at the time this application was filed were well aware of the degenerate genetic code. Thus, a disclosure of the amino acid sequence of the delta-6-desaturase inherently describes every possible nucleic acid sequence which encodes it.

The Examiner states that "the specification discloses SEQ ID NO: 1, yet there is no evidence provided that SEQ ID NO: 1 encodes a delta-6-desaturase." On the contrary, however, the specification clearly discloses the sequence which had been introduced into the vector pBICH3 to obtain the expression construct pBDES6 (example 7) as well as the use of this

construct for successful transformations. NsiI and BamHI restriction sites are disclosed to have been inserted flanking the start and stop of the sequences encoding the Tetrahymena delta-6-desaturase, and the restricted fragments are disclosed to have been inserted into the linearized vector pBICH3 (p. 30, 1. 5-25). The start and stop codons are defined by positions 33 and 1091 of SEQ ID NO: 1, respectfully (p. 9, 1. 17-24). There are no further start codons (ATG) in 5' direction of the start position 33 so that the sequence inserted in pBICH3 does not differ from SEQ ID NO: 1 with regard to function.

Thus, those of ordinary skill in the art would be able to recognize from the teaching of the present specification that nucleotides 33-1091 of SEQ ID NO:1 are present in pBDES6. This can also be understood from the primers used (D6-Nsi-F and D6Bam-R; p. 30, 8-18). The forward primer F6-Nsi-F already possesses an internal start codon so that, in the strict sense, it comprises SEQ ID NO: 1 only starting from nucleotide 39.

The specification teaches that the delta-6-desaturase encoding sequence contained in plasmid pBDES6 was successfully transformed into Tetrahymena cells (see example 8; p. 31, 1. 33-35; and p. 32, 1. 6-9). Table 2 shows increased production of GLA as a result of successful transformation of the pBDES6 construct into Tetrahymena cells. Particularly interesting is a moderate increase of the production of C18:2 fatty acids and a stronger increase in the production of GLA which is a C18:3 fatty acid. The latter effect is due to increased delta-6-desaturase activity which can be taken from Fig. 1.

Accordingly, the rejection is seen to be without merit, and should be withdrawn.

**VI. The Rejection of Claims 1, 3-6, 8-10, 14-30 and 33 Under 35 U.S. C. § 112 –
Enablement Requirement**

Claims 1, 3-6, 8-10, 14-30 and 33 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Claims 17, 18, and 30 have been canceled. The rejection of claims 1, 3-6, 8-10, 14-16, 19-29, and 33 is respectfully traversed.

Claim 1 as amended is directed to nucleic acids encoding *Tetrahymena* delta-6-desaturase as shown in SEQ ID NO:2. As explained above, the specification inherently discloses every possible nucleic acid sequence which encodes SEQ ID NO:2. The Examiner asserts that “the specification does not disclose any sequences having delta-6-desaturase activity” and “that there is [no] description of SEQ ID NO: 1 provided in a construct and transformed into an organism or the increase of delta-6-desaturase activity in a transformed organism.” On the contrary, however, as discussed above, the specification clearly discloses the sequence which had been introduced into the vector pBICH3 to obtain the expression construct pBDES6 (example 7) as well as the use of this construct for successful transformations. The partial sequence SEQ ID NO: 1 (nt 33-1091) contained in plasmid pBDES6 is disclosed to have been successfully transformed into *Tetrahymena* cells (see example 8; p. 31, l. 33-35; and p. 32, l. 6-9). NsiI and BamHI restriction sites are disclosed to have been inserted flanking the start and stop of the sequences encoding the *Tetrahymena* delta-6-desaturase, and the restricted fragments are disclosed to have been inserted into the linearized vector pBICH3 (p. 30, l. 5-25). The start and stop codons are defined by positions 33 and 1091 of SEQ ID NO: 1, respectfully (p. 9, l. 17-24). There are no further start codons (ATG) in 5’ direction of the start position 33 so that the sequence inserted in pBICH3 does not differ from SEQ ID NO: 1 with regard to function.

Table 2 shows increased production of GLA as a result of successful transformation of the pBDES6 construct into *Tetrahymena* cells. Particularly interesting is a moderate increase of the production of C18:2 fatty acids and a stronger increase in the production of GLA which is a C18:3 fatty acid. The latter effect is due to increased delta-6-desaturase activity which can be taken from Fig. 1.

Accordingly, the rejection is seen to be without merit, and should be withdrawn.

VII. The Rejection of Claim 30 Under 35 U.S.C. § 102(b)

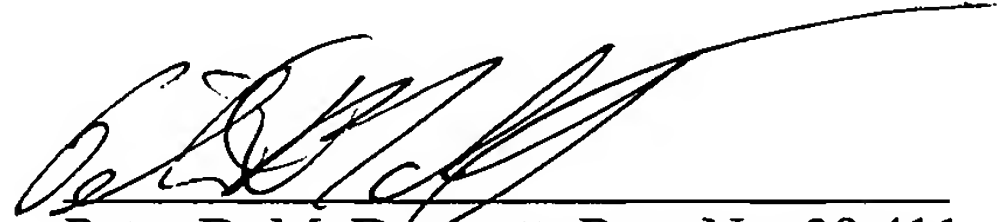
Claim 30 is rejected under 35 U.S.C. § 102(b) as being anticipated by Thomas (US Patent 5,614,393). Claim 30 has been canceled to advance prosecution.

Conclusion

Applicants respectfully request consideration of the application and allowance of the claims.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'Peter D. McDermott', written over a horizontal line.

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